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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,321	08/10/2001	Dirk Walther	ICYTP011	4696

22434 7590 12/29/2003

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,321

Applicant(s)

WALTHER ET AL.

Examiner

Channing S Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 29-61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 10-14 and 20-23 is/are allowed.
- 6) ☒ Claim(s) 5-9, 15-19 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 and 18 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 Sheets.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1631

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election without traverse of Group I (claims 1-28; drawn to a method, computer program product, and computing device for determining a sequence of a nucleic acid polymer) is acknowledged. Claims 29-61 are withdrawn from examination as not directed to the elected invention.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-28.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9, 15-19, and 24-28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Vague And Indefinite

Claims 5 (line 2), 15 (line 2), and 24 (line 2) contain the trademark/trade name MegaBACE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 U.S.P.Q. 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or

Art Unit: 1631

describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a capillary sequencing machine and, accordingly, the identification/description is indefinite.

Claims 6, 16, 25, and all claims dependent therefrom recites the further limitation of “generating at least one quality score for at least one basecall” which is confusing. Instant claims 1, 11, and 20 recite the final limitation (i.e. step) “determining the sequence of the nucleic acid polymer by assigning basecalls to the peaks. It is acknowledged the specification discloses basecall assignment to peaks as:

“...base calling is conducted, i.e., the determined peaks are assigned a base. Basecalls are assigned to all detected local maxima of LT according to:

$$(5) \text{ Base} = \max_{\text{base}=\text{A,C,G,T}} (S_{\text{base}}) \text{ with } S_{\text{base}} = R[\text{base}, \text{loc}] * A[\text{base}, \text{loc}] / \sum_{j=1}^4 A[j, \text{loc}]$$

where R(base,loc) are the peak shape factors obtained from Eq. 1, A is the area underneath a trace in a window of 7 trace pixels centered at loc. Effectively, the base with the maximal fractional area at a given peak location is chosen weighted by how peak-like the trace of a given base is (factor R). If the assigned base is the third or fourth base when traces are sorted according to decreasing fractional area at the current location alone (without factor R), an "N" (for not determined) is assigned to the current peak.” (page 14, lines 6-17 of the Specification).

Further, the specification discloses the calculation of quality scores and states:

“Equally important as the actual basecalls are associated quality scores that allow an assessment of the reliability of the call and to discriminate high-quality from low-quality calls. The present invention distinguishes between two different quality scores: the quality of the call, and the quality of the space between calls (gap-quality) as an indication that a true base may not have been called. The gap-quality score provides an estimate of the probability that a basecall has been missed, i.e.,

Art Unit: 1631

a probability that a deletion error has occurred during base calling. Use of the gap-quality score in the alignment process provides improved results by allowing accurate assignment of deletion errors during alignment. As such, the gap-quality may be used to identify deletion SNPs (Single Nucleotide Polymorphisms) where a potential base deletion needs to be distinguished reliably from a basecall error.” (page 14, lines 20-29 of the Specification).

However, the “further comprising” limitations of claims 6, 16, and 25 are confusing since the specification indicates quality scores (i.e. gap quality) simply assesses the basecall and fails to indicate any utilization of quality scores in the determination of the sequence of the nucleic acid polymer by assigning basecalls to the peaks. Clarification of the metes and bounds, via clearer claim language, is requested.

EXAMINER'S COMMENT

For the purposes of any applicable prior art the Examiner has interpreted “cross-correlation coefficient” and “ideal, Gaussian-shaped peak” as being limited to:

“The cross-correlation coefficient r is computed as:

$$(2) \quad r = (1/(N+1)) \sum_i \left\{ \frac{(T[base, loc-i] - MP(i)) * (T[base, loc-i] - MP(i))}{\sigma_T \sigma_{MP}} \right\},$$

with $-1 \leq r \leq +1$; and $-N/2 \leq i \leq +N/2$

where σ_T and σ_{MP} are standard deviations of T and MP , respectively. N is the number of trace locations in the considered segment, preferably, $N = 6$, i.e. a window of 7 trace points. If the number of trace points per initially assigned base call before quality filtering drops below 7, N is adjusted to $N = 4$ to account for somewhat undersampled chromatograms. r is set to zero for both of the terminal 3 trace points.

“The model peak is taken as an ideal Gaussian with:

$$(3) \quad MP(i) = \frac{1}{\sqrt{2\pi}\sigma} \exp\left(-\frac{1}{2}\left(\frac{i}{\sigma}\right)^2\right)$$

Art Unit: 1631

The specification discloses "cross-correlation coefficient" and "ideal, Gaussian-shaped peak" are limited to the above; no other information is provided. Given the above limitations no applicable prior art was found.

ALLOWABLE CLAIMS

Claims 1-4, 10-14, and 20-23 are found allowable.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380 (until 12 January 2004) and (571) 272-0717 (after 12 January 2004). The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/927,321

Page 6

Art Unit: 1631

Date: *December 23, 2003*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
Art 1631